Los Angeles Regional
Office of Public Affairs

Los Angeles, CA
310-268-4207

Department of Veterans Affairs

News Release

For further information,
please contact James Sola at
(208) 422-1104

Landmark VA Study Confirms Antibiotic Linezolid Is Effective Treatment for MRSA Infections

Los Angeles, Calif. (May 29, 2002) – In the largest comparator-controlled study investigating treatments for methicillin-resistant *Staphylococcus aureus* (MRSA) infections conducted to date, research led by the U.S. Department of Veterans Affairs (VA) shows that linezolid is a safe and effective alternative to standard therapy, vancomycin, for many serious MRSA infections. These include complicated skin and soft tissue infections and hospital acquired pneumonia; patients with urinary tract infections and bacteremia were also studied.

Results from the study, titled "Linezolid Versus Vancomycin injection for the Treatment of Methicillin-Resistant *Staphylcoccus aureus* (MRSA) Infections," are published in the June 1 issue of *Clinical Infectious Diseases*. Linezolid (ZYVOX™ injection and tablets) is the first from a completely new class of antibiotics to reach the market in more than three decades, the oxazolidinones. It has a mechanism of action unlike any currently available antibiotic.

"This study is the latest to evaluate the many potential applications for this new antibiotic. We now have conclusive evidence that linezolid is as effective as vancomycin in MRSA infections, with the added advantage to the clinician and patient of being used either IV or orally, " said Dr. Dennis Stevens, lead investigator and Chief, Infectious Diseases, Boise VA Medical Center. "The

availability of an oral agent with efficacy against MRSA infection provides a welcome alternative to IV therapy and may mean that some patients may get home from the hospital sooner."

460 patients with suspected or proven MRSA infections were enrolled in this trial at 104 sites in North America, Europe, Latin America and Asia. Patients were randomly assigned to either the linezolid (n=240) or vancomycin (n=220) treatment group and patients in both groups were matched closely in demographics, geographical location and physical characteristics.

Patients were randomized to receive either IV linezolid 600 mg every 12 hours or vancomycin 1g IV every 12 hours for at least seven days. After clinical improvement, linezolid IV-treated patients could be switched to oral linezolid 600 mg every 12 hours at the discretion of the investigator. In this study, 61 percent of the patients receiving linezolid were switched to the oral therapy, most within 5 days of treatment.

Linezolid was found to be clinically and microbiologically as effective as standard vancomycin therapy in patients initially hospitalized with MRSA infections, including skin and soft tissue infections and hospital-acquired pneumonia. Earlier data published from this MRSA study have shown that oral linezolid use resulted in a five-day decrease in hospital length of stay for patients with skin and soft tissue infections compared to vancomycin, suggesting potential patient and economic benefits following conversion to oral linezolid for the treatment of MRSA infections.

Linezolid-resistance to *Staphylococcus aureus* was not detected in this or any other clinical trial to date. Additionally, both regimens were well tolerated by the patients, with no observed difference in the number or type of adverse events.

"As MRSA infection rates have continued to rise at alarming rates in hospitals and communities, physicians have needed newer antibiotics with proven efficacy," said Dr. Stevens.

IV to Oral Conversion

Hospital length of stay has been linked to increased risk of serious hospital infections, including MRSA, because prolonged hospital stays often result in both extensive IV therapy provided through a catheter and exposure to other patients or healthcare workers who harbor resistant organisms. Indwelling devices, such as catheters, are the number one external cause of hospital-acquired infections each year.

Accordingly, recent guidelines issued by the Centers for Disease Control and Prevention (CDC) to prevent antimicrobial resistance advocate avoiding the use of unnecessary IV treatments and corresponding catheterization. One way to do this is by using an oral treatment in place of an IV, where appropriate. Oral linezolid offers a convenient and effective alternative to IV vancomycin therapy, as proven by this study.

Additional Information

- The CDC estimates that each year nearly 2 million patients in the United States acquire infections in hospitals, and the proportion of pathogens that are resistant to standard antimicrobial drugs continues to increase at an alarming rate.

- Currently, more than 50 percent of *Staphylococcus aureus* isolates causing infections in hospital intensive care units are resistant to methicillin treatment, and in other hospital settings more than 40 percent of *Staph* infections are caused by MRSA.

- According to the CDC, the financial burden of treating hospital-acquired infections caused by common forms of resistant bacteria, like *S. aureus*, is estimated to be more than $1 billion annually.

- The CDC recommends judicious use of vancomycin in their latest guidelines to help prevent antimicrobial resistance in hospital settings.

ZYVOX is indicated for the treatment of adult patients with susceptible strains of designated organisms, including patients with nosocomial pneumonia and skin and skin structure infections caused by methicillin-resistant *Staphylococcus aureus* infections.

Patients receiving linezolid should have complete blood counts monitored weekly, since myelosuppression has been reported. This applies particularly to those who: receive linezolid for longer than two weeks; have pre-existing myelosuppression; are receiving concomitant drugs that produce bone marrow suppression; or have a chronic infection and have received previous or concomitant antibiotic therapy.

Stevens and his colleagues report this study in the June issue of *Clinical Infectious Diseases*. Co-authors include Daniel Herr, Harry Lampiris, John Lee Hunt, Donald H. Batts, Barry Hafkin and the Linezolid MRSA Study Group. Their research was supported by Pharmacia Corporation.

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Media Contact: James Sola at (208) 422-1104
Shelly Wilt at (312) 240-2839